they file their new entrant reports prior to assuming Government responsibilities.

Each filing is estimated to take an average of one and one-half hours. The number of private citizens whose reports are filed each year with OGE is less than 10, but pursuant to 5 CFR 1320.3(c)(4)(i), the lower limit for this general regulatory-based requirement is set at 10 private persons (OGE-processed reports). This yields an annual reporting burden of 15 hours, the same as in the current OMB inventory for this information collection. The remainder of the private citizen reports are filed with other departments and agencies throughout the executive branch.

Public comment is again invited on each aspect of the proposed new OGE Form 450 as set forth in this second notice, including specifically views on the need for and practical utility of this proposed modified collection of information, the accuracy of OGE's burden estimate, the enhancement of quality, utility and clarity of the information collected, and the minimization of burden (including the use of information technology). The Office of Government Ethics, in consultation with OMB, will consider all comments received, which will become a matter of public record.

Approved: November 30, 1995.

Donald E. Campbell,

Deputy Director, Office of Government Ethics.

[FR Doc. 95–29723 Filed 12–5–95; 8:45 am]

BILLING CODE 6345–01–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 95D–0377]

Advertising and Promotion; Draft Guidances

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing two draft guidance documents entitled ''Guidance to Industry on Dissemination of Reprints of Certain Published, Original Data'' and ''Guidance for Industry Funded Dissemination of Reference Texts.'' These draft guidances are related to the dissemination, by sponsors of human and animal drugs, medical devices, and biological products, of certain reprints of journal articles discussing FDA-approved products, and reference texts (medical textbooks and compendia). The draft guidances describe circumstances under which the agency would exercise its discretion to allow the dissemination of these reprints and reference texts to health care professionals.

DATES: Written comments by January 5, 1996.

ADDRESSES: Submit written comments on the draft guidance documents to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, or FAX at 301–594–3215.

FOR FURTHER INFORMATION CONTACT: Ilisa B. G. Bernstein, Office of Policy (HF–23), Food and Drug Administration, 5600 Fishers Lane, rm. 15–74, Rockville, MD 20857, 301–827–3380, or via internet at IBernste@bangate.fda.gov.

SUPPLEMENTARY INFORMATION: Health care professionals have always been able to obtain, from a number of different sources, journal articles and reference texts (i.e., medical textbooks and compendia), that discuss human and animal drugs, medical devices, and biological products. These journal articles and reference texts are commercially available and may be obtained from publishers, libraries, on-line data bases, colleagues, bookstores, companies upon request, or other sources. Sponsors of human and animal drugs, medical devices, and biological products frequently have expressed a desire to disseminate reprints of journal articles and reference texts to health care professionals.

FDA traditionally has taken the position that sponsors who wish to distribute articles and reference texts containing information that is inconsistent with the FDA-approved labeling for a product may be in conflict with the Federal Food, Drug, and Cosmetic Act and implementing regulations. The agency's position is based on its mission to help ensure the safety and efficacy of human and animal drugs, medical devices, and biological products. Sponsors seeking approval or clearance to market these products must demonstrate to FDA that the products are safe and effective for their intended use(s). Permitting sponsors to freely disseminate information that is inconsistent with the FDA-approved or cleared use(s) would diminish the incentive for sponsors to perform the clinical studies which are necessary to verify that the product is safe and effective for the unapproved use. Furthermore, information disseminated by a biased source may have a greater potential to mislead the health care professional.

FDA believes that journal articles and reference texts are often useful to health care professionals. Accordingly, the agency has reviewed its policies to determine if modifications can be made without jeopardizing the integrity of the statutorily mandated standard that marketed drugs be safe and effective and have adequate directions for their intended use(s). After careful review, the agency is proposing to modify two of its policies at this time.

First, under one proposed draft guidance, the agency would allow sponsors to disseminate, under certain circumstances, journal articles that report the results of well-controlled studies, provided they represent the peer-reviewed, published version of original efficacy trials used to support approval, licensure, or clearance. Second, under the other proposed draft guidance, the agency would allow sponsors to disseminate, under certain circumstances, reference texts that discuss human or animal drugs, medical devices, or biological products. FDA has prepared two draft guidance documents describing the proposed circumstances under which the agency would exercise its discretion regarding the dissemination of these materials by sponsors.

FDA is particularly interested in receiving comments on whether the reprints discussed in the ''Guidance to Industry on Dissemination of Reprints of Certain Published, Original Data'' should be from ''peer-reviewed'' journals. If so, please comment on what constitutes a ''peer-reviewed'' journal and what benefits would be afforded if these reprints are from ''peer-reviewed'' journals.

Interested persons may, on or before January 5, 1996, submit to the Dockets Management Branch (address and FAX number above) written comments on the draft guidance documents. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance documents and received comments are available for public examination in the office above between 9 a.m. and 4 p.m., Monday through Friday.

The texts of the draft guidance documents follow:

Guidance to Industry on Dissemination of Reprints of Certain Published, Original Data[1]

I. Purpose of Guidance

Sponsors frequently want to disseminate reprints of articles reporting the results of the effectiveness trials that have been relied on by FDA in its approval or clearance of a drug, device, or biologic product. However, such articles may contain effectiveness rates, data, analyses, uses, regimens, or other information that is different from the approved labeling, and might, if disseminated by the sponsor, be considered violative promotional activities.

Nonetheless, the agency intends to allow the dissemination of reprints of articles that represent the peer-reviewed, published version of original efficacy trials, under the circumstances described in section II. below.

II. Circumstances for Dissemination of Certain Journal Articles Discussing FDA-Approved Products

1. The principal subject of the article should be the use(s) or indication(s) that has been approved by FDA. The article should be published in accordance with the regular peer-review procedure of the journal in which it is published, and the article reports the original study that was represented by the sponsor, submitted to FDA, and accepted by the agency as one of the adequate and well controlled studies providing evidence of effectiveness. In the case of a medical device, this guidance also applies to studies that were otherwise represented by the sponsor, submitted to the agency, and accepted by the agency as valid and material evidence of safety or effectiveness in lieu of adequate and well controlled studies;

2. The reprint should be from a bona fide peer-reviewed journal. A bona fide peer-reviewed journal is a journal that utilizes experts to review and objectively select, reject, or provide comments about proposed articles. Such experts should have demonstrated expertise in the subject of the article under review, and be independent from the journal;

3. If the article contains effectiveness rates, data, analyses, uses, regimens, or other information that is different from approved labeling, the reprint should prominently state the difference(s), with specificity, on the face of the reprint. One acceptable means of achieving the appropriate prominence for this statement is to permanently affix to the reprint a sticker stating the differences; and

4. The reprint should disclose all material

[1]This guidance does not apply to reprints of articles that discuss the specific prohibited uses of animal drugs listed in the FDA, Center for Veterinary Medicine Compliance Policy Guide 7125.06 or the Animal Medicinal Drug Use Clarification Act implementing regulations. Although this guidance does not create or confer any rights on any person and does not operate to bind FDA in any way, it does represent the agency's current thinking on the dissemination of reprints of certain published, original data. The agency will consider individual circumstances on a case-by-case basis.

Guidance for Industry Funded Dissemination of Reference Texts[2]

I. Purpose of Guidance

Sponsors have also expressed a desire to disseminate reference texts, i.e., medical textbooks and compendia, to health care professionals. These texts typically discuss a wide range of medical diagnoses and treatments, including drug product utilization, surgical techniques, and other medical topics. FDA recognizes that such texts are often useful to clinicians in the practice of medicine.

Reference texts often contain information about the use of drugs, devices, or biologic products in the treatment, diagnosis, or prevention of disease that may not be consistent with the FDA-approved labeling for the products (e.g., discussion of unapproved uses). FDA recognizes, however, that many textbooks do not necessarily highlight a particular drug or device manufacturers products. In such instances, industry's desire to disseminate these reference texts may be in conflict with the Federal Food, Drug, and Cosmetic Act (the act) and implementing regulations.[3]

Nonetheless, FDA intends to permit the distribution of sound, authoritative materials that are written, published, and disseminated independent of the commercial interest of a sponsoring company and are not false nor misleading. FDA, therefore, intends to allow the dissemination by sponsors of reference texts that discuss human or animal drug, device, or biologic products, under the circumstances described in section II. below.

II. Circumstances for Dissemination of Reference Textbooks

1. The reference text should not have been written, edited, excerpted, or published specifically for, or at the request of, a drug, device, or biologic firm (see discussion below);

2. The content of the reference text should not have been reviewed, edited, or significantly influenced by a drug, device, or biologic firm, or agent thereof (see discussion below);

3. The reference text should not be distributed only or primarily through drug, device, or biologic firms (e.g., it should be other distribution channels where similar books are normally available);

4. The reference text should not focus primarily on any particular drug(s), device(s), or biologic(s) of the disseminating company, nor should it have a significant focus on unapproved uses of the drug(s), device(s), or biologic(s) marketed or under investigation by the firm supporting the dissemination of the text; and

5. Specific product information (other than the approved package insert) should not be physically appended to the reference text.

The agency recognizes that there are some useful reference texts that are written, edited, or published by a sponsor or agent of the sponsor. In these instances, FDA intends to allow the distribution of a reference text under the circumstances described in paragraphs 3 through 5 above, when the authorship, editing, and publishing of the reference text results in the presentation of a balanced perspective of the subject matter. Typically, this would be evidenced by an authorship and editorial process that fosters input from a relatively wide spectrum of sources and that allows for information from all sources to be considered.

[2]Although this guidance does not create or confer any rights, on any person, and does not operate to bind FDA in any way, it does represent the agency's current thinking on industry funded dissemination of reference texts. Although FDA believes that this guidance encompasses the vast majority of reference texts, the agency will consider, on a case-by-case basis, reference texts that do not fall within the parameters of this guidance document. This guidance does not apply to textbooks or compendia that discuss the specific prohibited uses or animal drugs listed in the Center for Veterinary Medicine Compliance Policy Guide 7125.06 or the Animal Medicinal Drug Use Clarification Act implementing regulations.

[3]Printed materials, such as medical textbooks and compendia, which supplement, explain, or are textually related to a regulated product are considered labeling for that product when disseminated by or on behalf of the manufacturer, packer, or distributor of the product. See section 201(m) of the act (21 U.S.C. 321(m)) and *Kordel* v. *United States*, 338 U.S. 345, 350 (1948).

Dated: November 30, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95–29663 Filed 12–1–95; 1:21 pm]

BILLING CODE 4160–01–F

National Institutes of Health

National Institute of Mental Health; Notice of Closed Meetings

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings of the National Institute of Mental Health Special Emphasis Panel:

Agenda/Purpose: To review and evaluate grant applications.

Committee Name: National Institute of Mental Health Special Emphasis Panel

Date: December 5, 1995.

Time: 3 p.m.

Place: Parklawn Building, Room 9C–18, 5600 Fishers Lane, Rockville, MD 20857.

Contact Person: Phyllis L. Zusman, Parklawn Building, Room 9C–18, 5600 Fishers Lane, Rockville, MD 20857, Telephone: 301, 443–1340.

Committee Name: National Institute of Mental Health Special Emphasis Panel

Date: December 11, 1995.

Time: 1:30 p.m.

Place: Parklawn Building, Room 9C–18, 5600 Fishers Lane, Rockville, MD 20857.

Contact Person: Michael D. Hirsch, Parklawn Building, Room 9C–18, 5600 Fishers Lane, Rockville, MD 20857, Telephone: 301, 443–1000.

Committee Name: National Institute of Mental Health Special Emphasis Panel.